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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/887,505	07/02/1997	ROBERT L. KILKUSKIE	HYZ-040CIP	1117

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HALE AND DORR
60 STATE STREET
BOSTON, MA 02109

EXAMINER
TAYLOR, JANELL E

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/887,505	Applicant(s) BUCHANAN ET AL.	
	Examiner Janell Taylor Cleveland	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,25,27-31 and 42-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *22-24 and 26* is/are allowed.

6)☒ Claim(s) *1-21, 25, 27-31, and 42-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The following rejection is **FINAL**. Any rejection not reiterated is withdrawn. A "Response to Arguments" section follows.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a pharmaceutical composition comprising at least two different oligonucleotides according to claim 2 in a pharmacologically acceptable carrier. However, claim 2 does not teach two different oligonucleotides. Claim 2 teaches only one oligonucleotide, which is complementary to two noncontiguous regions. Therefore, it is not clear what two different oligonucleotides claim 43 refers to. Clarification is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Cha et al.

Cha et al. disclose SEQ ID NO: 126 which is identical to SEQ ID NO: 117 of the instant application. In particular, bases 10-29 of Cha are identical to bases 1-20 of the instant application. Therefore, Claim 1 is fully anticipated by Cha et al. Cha also teaches "the non-naturally occurring peptides of the present invention are useful as a component of a vaccine." (Col. 6, lines 11-12). Cha also teaches "The preparation of vaccines which contain an immunogenic peptide as an active ingredient, is known to one skilled in the art. Typically, such vaccines are prepared as injectables, either as liquid solutions or suspensions; solid forms suitable for solution in, or suspension in, liquid prior to injection may also be prepared...The active immunogenic ingredients are often mixed with excipients which are pharmaceutically acceptable and compatible with the active ingredient." (Col. 12, bridging col. 13). Cha et al. therefore fully anticipates claim 44.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-6, 8-20, 25, 27, 28, 30 and 43 are rejected under 35 U.S.C. 103(a) as being disclosed by Hogan, et al in US Patent 5,424,413 in view of Maertens et al. (US Patent 5,846,704).

These claims are drawn to an oligonucleotide comprising a sequence complementary to at least two non-contiguous regions of an HCV mRNA or genomic RNA. Claim 43 is drawn to a pharmaceutical composition.

Hogan discloses a nucleic acid hybridization probe having at least one nucleic acid strand which has at least two separate target specific regions that hybridize to a target nucleic acid sequence. (See Abstract, Drawing 4A). This patent also discloses the use of modified oligonucleotides, as well as therapeutic applications for oligonucleotides (which may be used in pharmaceutical applications, see Cols. 25-26).

This patent does not disclose an HCV messenger or genomic RNA.

Maertens et al. disclose as their invention probes targeting sequences from the 5' untranslated region of HCV. (See Abstract).

One of ordinary skill in the art would have been motivated to target the probe of Hogan et al to an HCV messenger or genomic RNA because Maertens et al disclosed the importance of detecting HCV nucleic acids. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

7. Claims 7, 31, 43, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. in view of Maertens et al. and further in view of Seki et al (CA2104649).

These claims are drawn to an oligonucleotide as described above, further comprising the specific recited sequences, including SEQ ID NO: 47 and 160. Claims 43 and 45 are drawn to pharmaceutical compositions.

The teachings of Hogan et al. and Maertens et al are discussed above.

These references do not disclose the specific nucleic acid sequence of the claims.

Seki et al. disclose an oligonucleotide (SEQ ID NO: 6) identical to instant SEQ ID NO: 47. Seki et al also disclose an oligonucleotide (SEQ ID NO: 229) identical to instant SEQ ID NO: 160. Seki et al. also discloses that these nucleic acids may be intravenously administered to human subjects (as a pharmaceutical composition.) (Page 16).

One of ordinary skill in the art would have been motivated to use probes containing the sequences of the cited references, or obvious variations thereof, in the oligonucleotides as discussed above because these would have clearly been useful in detecting HCV nucleic acids.

8. Claims 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. in view of Maertens et al. and further in view of Cha et al (USPN 6,071,693).

These claims are drawn to an oligonucleotide as described above, further comprising the specific recited sequences, including SEQ ID NOS: 122 and 117.

The teachings of Hogan and Maertens et al are discussed above.

These references do not disclose the specific nucleic acid sequence of the claims.

Cha et al. disclose an oligonucleotide (SEQ ID NO: 126), identical to instant SEQ ID NO: 122.

One of ordinary skill in the art at the time of the invention would have been motivated to use probes containing the sequences of the cited references, or obvious variations thereof, in the product as discussed above because these would have clearly been useful in detecting HCV nucleic acids.

Response to Arguments

9. Applicant's arguments filed September 6, 2002 have been fully considered but they are not persuasive.

First, Applicant addresses the rejection under 35 U.S.C. 112, second paragraph. Applicant's amendment does not overcome the rejection. The rejection is based on the fact that claim 43 is drawn to a pharmaceutical composition comprising *at least two* different oligonucleotides according to claim 2, but claim 2 does not teach two different oligonucleotides. Claim 2 teaches only one oligonucleotide, which is complementary to two noncontiguous regions. Therefore, it is not clear what two different oligonucleotides claim 43 refers to. Applicant's amendment does not solve this problem.

Next, Applicant argues that the rejection of the claims based on the art of Cha is inappropriate because SEQ ID NO: 126 disclosed in Cha et al. is only partially identical to SEQ ID NO: 117. However, the way the claims are worded, there is a discrepancy between the SEQ ID NOS and the tables referred to by the claim. Cha teaches the sequence found in the SEQ ID NOS, and therefore is appropriately applied. Although

the table teaches a mutation of SEQ ID NO: 117, it does not teach SEQ ID NO: 117, as is claimed, and therefore the claim is contradictory.

Applicant also argues that the rejection of claims 2-6, 8-20, 27, 28, 30, and 43 is inappropriate. Applicant has argued that the Hogan et al. reference teaches contiguous nucleic acids and therefore the rejection is inappropriate, as the claims read on noncontiguous nucleic acids. However, in column 3 of the Hogan et al. patent, it states that "The one or more nucleic acid molecules or the target nucleic acid may include nucleic acid adjacent the junction which does not form a duplex with the arm regions or the target regions or the target nucleic acid, and loops out from the junction. Alternatively, the target regions include along their length, or at the ends distant from the arm regions, nucleic acid which does not from a duplex with the target nucleic acid and therefore either loops from a duplex formed between the target nucleic acid and the target region, or extends as a single stranded region from the end of the target region." (lines 17-28). Therefore, Hogan et al. teaches that the nucleic acid need not be contiguous.

Applicant also argues that the rejection of claims 7, 31, 43, and 45 are inappropriate. Applicant argues that the Seki art is inappropriately applied because the sequences of Seki are only partially identical to the sequences of the instant claims. However, Seki teaches all of SEQ ID NO: 47. Although Seki does not teach "at least two non-contiguous regions" of an HCV messenger genome, this is why the art of Hogan and Maertens was relied upon.

Since the rest of the arguments are based upon those presented above, they are not specifically addressed.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiries of a general nature relating to this application, including information on IDS forms, status requests, sequence listings, etc. should be directed to the Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 872-9306 or 872-9307 (after final). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

October 23, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600